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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,089	08/21/2003	David Ernest Hartley	PA-5340 -RFB	7302
9896	7590	02/16/2006	EXAMINER	
COOK GROUP PATENT OFFICE			ROGERS, KRISTIN D	
P.O. BOX 2269			ART UNIT	
BLOOMINGTON, IN 47402			PAPER NUMBER	

3736

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/645,089

Applicant(s)

HARTLEY ET AL.

Examiner

Kristin D. Rogers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

### ***Priority***

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60405161, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application 60405161

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discloses a radius of curvature for the pre-formed bend at the distal end of the guidewire in the range of five to fifteen centimeters. In contrast, Application 10645089 discloses the claimed invention having a radius of curvature of five to twenty millimeters. Since the claimed range is not within the range specified by Application 60405161, accordingly, claims 15 and 21 are not entitled to the benefit of the prior application.

### ***Specification***

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: VARIABLE STIFFNESS ATRAUMATIC GUIDEWIRE.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16, lines 8-9 fail to clarify the particulars of the distal

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portion being claimed. "...comprising in order from the central zone; and ..." is indefinite. Appropriate action is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1,4-5,8-10,12,16-17,19,22-23,26 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al. (5421349). In regard to claims 1,22,30-34, Rodriguez et al. shows a guidewire for a medical device comprising an elongate central zone comprising of mandrel 11 of high stiffness (column 3, lines 62-63), tapered mandrel proximal zone of transition from high to semi-stiffness 20 (column 2, lines 7-11), and tapered distal zone of transition from high stiffness to flexible 14 (column 2, lines 66-68). The distal end 14 further comprises a pre-formed bend adjacent the distal end formed in a part circular shape (See Fig.1) and the proximal end is (column 2, lines 36-37 Fig. 2). In regard to claims 4-5,8,16-17,19,23,26 Rodriguez shows tapered mandrel proximal zone 20 with coil 30 extending its length, the coil being of substantially constant diameter (column 3, lines 26-29) formed into a rounded tip 32 (Figure 2). In regard to claims 9-10,12,16-17,19,23 Rodriguez et al. shows a tapered mandrel portion of distal zone 14 of constant reduced diameter 16 with coil 18 along the tapered distal mandrel of constant reduced diameter 16. Distal coil 18 is of substantially constant (column 2, lines 19-20) diameter terminating in a rounded tip (Figure 1).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2-3 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. in view Lafontaine (5662621). Rodriguez et al. shows a guidewire for a medical device comprising a distal end 14. Rodriguez et al. lacks a distal zone comprising three zones of varying stiffness. In regard to claim 2, Lafontaine teaches a guidewire for a medical device including a distal zone 22 comprising of three zones: Zone 1 semi-stiff adjacent central zone 24, Zone 2 transition zone, and Zone 3 of high flexibility. Lafontaine includes heating coils 60,62,64 for heating the zones respectively, thus varying the stiffness of the zones (Figure 3, column 6 lines 3-26). In regard to claims 3 and 27, Lafontaine teaches a central zone 24 comprised of stainless steel

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material (column 5, lines 64-67) for providing a zone of high stiffness. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Rodriguez with a distal tip having three transition zones of stiffness and a central zone made of stainless steel material since such modification would provide a guidewire with varying stiffness. The Examiner notes that Worley et al. (20030208141) teaches a guidewire with distal zone having three zones of stiffness (page 4, paragraphs 47-48 Figures 2 and 4).

12. Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. in view of Erickson et al. (5664580). Rodriguez et al. shows a guidewire for a medical device comprising proximal and distal zone wire coils 30 and 18 wherein the wire coils are epoxied or soldered to the proximal and distal mandrel (column 3, line 45). Rodriguez et al. lacks wire coils that are laser welded to the proximal and distal zone. In regard to claims 7 and 11, Erickson et al. teaches a guidewire for a medical device comprising proximal wire coil 22 and distal wire coil 24 attached to proximal and distal mandrel by laser spot-welding (column 6, lines 38-41) for the purpose of providing a strong attachment between the coil and the mandrel. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Rodriguez et al. with proximal and distal wire coils laser welded to the mandrel portion as taught by Erickson et al. for the purpose of providing a strong attachment between the coil and the mandrel.

13. Claims 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. as applied to claims 1 and 16 above in view of Worley et al

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(20030208141). Rodriguez et al. shows the elements of the claimed invention as set forth above including a distal end. Rodriguez et al. lacks disclosure of the radius of curvature of the distal end and the tip zone. In regard to claims 13 and 20, Worley et al. teaches a guidewire for a medical device with distal end having a radius of curvature of 63.5 millimeters that comprises a portion of the central zone 12, semi-stiff zone 34, and transition zone 36 (Figure 4, page 5 paragraph 59) for introducing the guidewire without damaging surrounding tissue. Therefore it would have been obvious to one having ordinary skill in the art to modify Rodriguez et al. with a distal end having a radius of curvature of 63.5 millimeters as taught by Worley et al. since such modification would provide a guide wire having a less traumatic distal end.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. and Lafontaine as applied to claim 2 above, and further in view of Worley et al. Rodriguez et al. shows the elements of the claimed invention as set forth above including a distal end. Rodriguez et al. lacks disclosure of the radius of curvature of the distal end and the tip zone. Worley et al. teaches a guidewire for a medical device with distal end having a radius of curvature of 63.5 millimeters that comprises a portion of the central zone 12, semi-stiff zone 34, and transition zone 36 (Figure 4, page 5 paragraph 59) for introducing the guidewire without damaging surrounding tissue. Therefore it would have been obvious to one having ordinary skill in the art to modify Rodriguez et al. with a distal end having a radius of curvature of 63.5 millimeters as taught by Worley et al. since such modification would provide a guide wire having a less traumatic distal end.



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15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. and Lafontaine as applied to claim 2 above, and further in view of Connors, III et al. (20040039304). Rodriguez et al. shows a distal end, but lacks disclosure regarding the tip zone conformation. Connors, III et al. teaches a guidewire with distal end having a pre-bent j-curve tip zone with radius of curvature of nine millimeters 110b (page 2, paragraph 0015, Figure 1) for the purpose of providing less damage to the vessel wall. Therefore it would have been obvious to one having ordinary skill in the art to modify Rodriguez et al. with a distal tip zone with a radius of curvature of nine millimeters as taught by Connors, III et al. for the since such modification would provide a guide wire having a less traumatic distal tip zone.

16. Claims 21,24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. in view of Connors, III et al. In regard to claims 21,24-25, Connors, III et al. teaches a guidewire with distal end having a pre-bent j-curve tip zone with radius of curvature of nine millimeters 110b (page 2, paragraph 0015, Figure 1) for the purpose of providing less damage to the vessel wall. Therefore it would have been obvious to one having ordinary skill in the art to modify Rodriguez et al. with a distal tip zone with a radius of curvature of nine millimeters as taught by Connors, III et al. for the since such modification would provide a guide wire having a less traumatic distal tip zone.

17. Claims 6,18 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. and Connors, III et al. as applied to claims 1, 16 and 21 above, and further in view of Cornelius et al. (5924998). Rodriguez et al. shows a guidewire for a medical device including proximal, central, and distal zone with a

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polytetrafluoroethylene coating. Rodriguez et al. lacks disclosure of the zones including a tapered coil and the coil being covered in polytetrafluoroethylene and a radiopaque marker. In regard to claim 6, Cornelius et al. teaches a tapered coil 243 (Figure 3) In regard to claims 18,28,29, Cornelius et al. teaches a guidewire comprising a coil 42 formed of stainless steel coated in polytetrafluoroethylene (PTFE) (column 4, lines 10-12) and a radiopaque distal tip 38 (column 3, lines 42-43) for making the coil hydrophobic and X-ray detectable. Therefore it would have been obvious to one having ordinary skill in the art to modify Rodriguez et al. with a tapered coil and a distal zone having a coil coated in PTFE and being radiopaque since such modification would provide a hydrophobic X-ray detectable distal tip.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDR

  
M. H. ROSENBERG  
PATENT EXAMINER  
10/11/2010